

REMARKS

Claims 1-9, 11-13, 19-23, 26, 27 and 29-35 were pending. Claims 1, 2, 19, 31, and 32 have been amended. Claims 13 and 33 has been canceled. After entry of this amendment, claims 1-9, 11-12, 19-23, 26, 27, 29-32, and 34-35 remain pending. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter is added.

Substance Of The Interview

Applicants thank the Examiner for the courtesy of the personal interview on February 17, 2010, with Applicants representatives, Mats Carlson, Martin Holmberg, and Brian Ho. Cited reference U.S. 6,468,222 (hereinafter "Mault") was discussed in particular. Applicants provided a demonstration of the NIOX MINO®, an asthma inflammation monitor manufactured by Aerocrine, the assignee of record. The NIOX MINO® is a NO measurement device that falls within the scope of at least present claim 1. Applicants believe that general agreement was reached with respect to claim amendments to address the 35 U.S.C. 112 rejections. Applicants believe that the present amendments, such as reciting an inhalation flow path and an exhalation flow path, fall within the scope of the general agreement reached with the Examiner with respect to addressing indefiniteness. Applicants also believe that general agreement was reached with respect to the patentability of the present claims over Mault, given amendments as presented herein which emphasize the absence in Mault of a buffer for holding a gas sample for a period of time and, consequently, the absence of a means for feeding such a buffered sample to an electrochemical sensor.

Claim Rejections Under 35 USC §112

Claims 1-9, 11-13, 29-30, and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Claims, As Amended, Are Definite

While Applicants believe that the previously presented claims were definite, Applicants have amended claim 1 (from which the remaining rejected claims depend) in accordance with the agreement reached with the Examiner.

In particular, claim 1 has been amended to specify that the “NO scrubber [is] connected to the combined inlet and outlet along an inhalation flow path” and to specify that the “buffer chamber [is] connected to the combined inlet and outlet along an exhalation flow path.”

Applicants note that definiteness of claim language must be analyzed in light of the content of the particular application disclosure. MPEP 2173.02. In that respect, Applicants respectfully assert that the one of skill would readily be able to understand the present claims in view of the specification as filed, particularly with respect Figure 1 and the accompanying text at page 5, line 15, to page 12, line 8.

Also, while Applicants have endeavored to present particular language that Applicants genuinely believe embodies the invention, Applicants note that the “focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” MPEP 2173.02. Applicants are, of course, willing to consider any suggested language that the Examiner may provide.

Applicants therefore assert that the present claims, particularly in view of the amendments, meet the requirements for definiteness. Further, while claim 19, and the claims that depend there from, are not currently rejected under 35 U.S.C. 112, second paragraph, Applicants have amended

claim 19 to also include an “inhalation flow path” and an “exhalation flow path,” per the recommendations of the Examiner.

For the reasons stated above, Applicants respectfully request that all rejections under 35 U.S.C. 112, second paragraph be withdrawn.

Claim Rejections Under 35 USC §102

Claims 1, 4-9, 12-13, 19-22, 26-27, 29, and 30-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,468,222 (“Mault”).

Mault Does Not Teach “A Buffer Chamber”

As discussed above, Applicants believe that general agreement was reached with respect to the differences between the claimed invention and the disclosure of Mault. In particular, Applicants believe that agreement was reached concerning Mault’s disclosure of an open flow path (albeit having some flow-resisting elements). Mault at col. 7, lines 9-40. As such, Applicants respectfully assert that Mault fails to teach a “buffer chamber configured to temporarily hold a sample of the exhalation air for a period of time.”

In the Office Action of December 8, 2009, the Examiner points to the flow tube (36) of Mault as a buffer chamber within the scope of the claim, in light of the present disclosure’s teaching that the buffer chamber may be formed “as a length of tubing.” Specification at page 11, lines 16-18.

Applicants assert that the term “buffer chamber,” in and of itself, has meaning to a person of skill in the art. In the context of gas handling and measurement, Applicants assert that one of skill in the art would understand the claim term “buffer chamber” (particularly in view of the additional language stating that the buffer chamber is “configured to temporarily hold a sample of the exhalation air for a period of time”) to refer to structure that must be able to hold a sample of gas for a period of time. So, while the buffer chamber may be formed as length of tubing, it must be configured in the device in such a way as to perform buffering and act as a buffer. In the non-limiting example of the present specification, such a function can be performed by configuring the buffer chamber with a flow regulator and valve, which allows holding of a gas sample. Those of skill in the art will understand that other configurations that create buffering may be employed, as long as the structure is capable of holding the gas sample.

In contrast, Applicants note that flow tube (36) of Mault is an open-ended structure that is incapable of temporarily holding a sample of gas. Both the top and the bottom of flow tube (36) open into unregulated spaces without structures for holding a sample of gas. As such, the device of Mault's incapable of buffering or holding a gas sample for any period of time. Rather, the sample enters and exits the device freely.

Mault Does Not Teach A "Means For Feeding The Temporarily Held Sample"

The absence of a buffer chamber, "configured to temporarily hold a sample of the exhalation air for a period of time," in Mault leads to the absence of another element of the claimed device: a "means for feeding the temporarily held sample of the exhalation air from the buffer chamber to the electrochemical NO sensor." This element, in combination with the buffer chamber and holding of the sample, directly relates to one of the advantages of the present device, as discussed in the specification:

One major advantage of the device and method according to the invention is the fact that it becomes possible to take a sample from a patient according to parameters dictated by the physiology of said patient . . . while performing the analysis of the sample according to parameters optimal for the chosen sensor.

Specification at page 21, lines 15-21. To paraphrase, the combination of the buffer chamber for holding a sample and the means for feeding that sample at a controlled rate, allows the claimed devices and methods to disassociate the optimal parameters for a sensor from the actual, physiological parameters of the patient. Accordingly, sensors which may perform sub-optimally under physiological conditions (e.g., electrochemical NO sensors) may be optimally employed in the present devices and methods.

The open, passive flow structure of Mault does not include a fan, pump, or equivalents thereof, for feeding the held gas sample to an electrochemical sensor. As such, the device of Mault cannot control the flow rate of sample to a sensor. Rather, the flow rate is dictated by the physiological parameters of the patient. Mault, in fact, teaches away from controlling the flow rate of the sample: "It is preferred that inhalations and exhalations are not restricted as they flow through the calorimeter." Mault at col. 7, lines 61-63. This is not surprising given the calorimetric functions

of the Mault device, which requires measurement of metabolic rates, including flow rates. Mault at col. 17, lines 20-50. As such, the Mault device does not, and should not, significantly alter the flow rate of the gas sample. Accordingly, the Mault device does not include the claimed “means for feeding the temporarily held sample.”

Mault Does Not Teach An “Electrochemical NO Sensor”

As discussed in the Response of August 13, 2009, Mault does not disclose an electrochemical NO sensor. Rather, Mault only provides a fleeting reference to NO measurement, without providing any specifics. Mault at col. 31, lines 49-53. The only reference made by Mault to electrochemical sensors refers to the use of an electrochemical oxygen sensor. Mault at col. 29, line 52. As such, Mault does not teach an electrochemical NO sensor.

Further with respect to electrochemical NO sensors, the current claims are directed to a device for “diagnostic NO measurements.” In the context of diagnostic gas measurements, Applicants note that measurements of oxygen and of NO differ dramatically due to radically different concentrations of the two gases in exhaled breath. One of skill recognizes that diagnostic measurement of oxygen is typically provided in percentage values (*i.e.*, parts per hundred). *Cf.* Mault at col. 18, lines 39-50. In comparison, diagnostic measurement of NO in exhaled breath typically requires measurement in parts per billion (ppb). Specification at page 5, lines 9-14. Accordingly, the general reference in Mault to NO measurement does not teach or enable diagnostic measurement of NO, particularly through the use of electrochemical sensors, which typically have optimal parameters that differ from physiological parameters, as discussed above.

While the above remarks have been made with respect to the language of claim 1, Applicants note that independent claims 19 and 31 contain similar limitations directed to a buffer chamber, holding a sample for a period of time, and feeding the held sample to a sensor at a flow rate different than the exhalation flow rate. For these reasons, and for the reasons presented in Applicants’ response of August 13, 2009, Applicants respectfully assert that Mault does not anticipate the present claims.

Applicants respectfully request that all the rejections under 35 U.S.C. 102(e) be withdrawn.

Claim Rejections Under 35 USC §103**Claims 2-3, 23, and 30 over Mault**

Claims 2-3, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault.

Applicants respectfully assert that Mault does not render the recited claims obvious for at least failing to teach or suggest all of the limitations of the claims, as discussed in the previous section.

Applicants respectfully request that the rejections of claims 2-3, 23, and 30 as being obvious over Mault be withdrawn.

Claims 14-15 and 18 over Mault in view of Holowko

Claims 14-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of U.S. Patent No. 6,039,251 ("Holowko").

Applicants note that claims 14, 15, and 18 have been cancelled. Applicants therefore respectfully request that the rejections of claims 14-15 and 18 as being obvious over Mault and Holowko be withdrawn.

Claim 11 over Mault in view of Birks

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of U.S. Patent No. 7,045,359 ("Birks").

Applicants respectfully assert that Birks does not address all of the deficiencies discussed above, with respect to Mault, so as to render the cited claims obvious. Notably, Birks teaches a reaction chamber 1 that is used to hold a sample for a period of time, the NO is held in the chamber for the purposes of reacting with O₃ (thereby depleting all of the NO). Birks at Figure 2 and at col. 4, lines 62-67. Ultimately, it is level of O₃, and not NO, that is measured by the device of Birks. *Id.*

This mechanism, which measures a surrogate gas rather than NO, is similar to the mechanism of EP 0904729, addressed in Applicants' Response of August 19, 2008. Because Birks does not measure NO, with an electrochemical sensor or any other type of sensor, Birks is silent on having a means for feeding a sample at a NO sensor-suitable flow rate that is lower than the exhalation flow rate.

Applicants therefore respectfully request that the rejection of claim 11 as being obvious over Mault and Birks be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 514862000700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 2, 2010

Respectfully submitted,

By /Brian B. Ho/

Brian B. Ho

Registration No.: 60,199

MORRISON & FOERSTER LLP

425 Market Street

San Francisco, California 94105-2482

Telephone: 415.268.7624

Fax: 415.268.7522